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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/637,142

08/08/2003

Show-Mean Wu

1001.1684101

3414

28075 7590 03/23/2009
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EXAMINER

HOLLOWAY, IAN KNOBEL

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

03/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/637,142

Applicant(s)

WU ET AL.

Examiner

IAN K. HOLLOWAY

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Receipt is acknowledged of applicant's amendment filed (10/22/2008). Claims 2-3 has been canceled without prejudice. Claims 1, 4-27 are pending and an action on the merits is as follows.

Applicant's arguments with respect to claims 1 and 4-27 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1, 4, 6-8, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Barbere (US Patent 6066157)**.in view of **Barath (US Patent 5616149)** and **Adams et al. (US patent 5941871)**, herein after referred to as **A**.

Regarding **Claim 1**, **Barbere** discloses an elongate catheter shaft, (**Fig. 1**, the catheter shaft) the shaft including an inner tubular member (**14**, the inner member, having a lumen) having an inner lumen extending therethrough, an outer tubular member, (**12**, the exterior tube) and an inflation lumen (**18**, the balloon) disposed between the inner tubular member and the outer tubular member; wherein the outer tubular member includes a plurality of distal openings; (**22**, multiple opening at the distal end) a balloon (**18**, the balloon) coupled to the shaft and disposed over the distal openings in the outer tubular member

Barbere fails to disclose one or more cutting members coupled to the balloon, wherein the plurality of distal openings are arranged about the outer tubular member in one or more longitudinally aligned sets, ere and wherein the one or more cutting members are radially aligned with the longitudinally aligned sets.

However, **Barath** teaches one or more cutting members (**6**, a cutting member) coupled to the balloon, wherein the distal opening is arranged about the outer tubular member in one or more longitudinally aligned sets, (**6 and 4, Fig. 3**, the right hand opening lines up with the cutting member) and wherein the one or more cutting members are radially aligned with the longitudinally aligned sets. (**6 and 4, Fig. 3**, the right hand opening lines up with the cutting member)

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to the construction design as taught by **Barath**, since **Barath** states at column 2, lines 15-16 and 45-48 that such modification would cause less damage to blood vessels. Thus, it would have been obvious to one of ordinary skill in the art to apply the construction as taught in **Barath**, to improve the catheter of **Barbere** for the predictable result of making the device safer to use.

The device of Barbere as modified by Barath fails to disclose the plurality of openings.

However **A** teaches a plurality of openings (**66**, 3 openings on each side can be seen)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a plurality of openings, since it has been held that a mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Regarding **Claim 4**, **Barbere** discloses: the inner tubular member extends distally beyond a distal end of the outer tubular member. (**10**, **Fig. 1**, the inner member is found continuing past the end of the outer).

Regarding **Claim 6**, **Barbere** discloses a catheter shaft (**Fig. 1**, the catheter shaft) having an inflation lumen extending at least partially therethrough; a first set of longitudinally aligned openings defined in the shaft; (**22**, multiple opening at the distal end) a second set of longitudinally aligned openings defined in the shaft; (**22**, multiple opening at the distal end) a balloon (**18**, the balloon) coupled to the shaft and disposed

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over the sets of openings, the balloon including an inner chamber (**12**, the tube is in fluid communication with the balloon) in fluid communication with the inflation lumen

Barbere fails to disclose a first cutting member coupled to the balloon and radially aligned with the first set of longitudinally aligned openings; and a second cutting member coupled to the balloon and radially aligned with the second set of longitudinally aligned openings

However, **Barath** teaches a first cutting member (**6**, a cutting member) coupled to the balloon and radially aligned with the first set of longitudinally aligned openings;

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to the construction design as taught by **Barath**, since **Barath** states at column 2, lines 15-16 and 45-48 that such modification would cause less damage to blood vessels. Thus, it would have been obvious to one of ordinary skill in the art to apply the construction as taught in **Barath**, to improve the catheter of **Barbere** for the predictable result of making the device safer to use.

The device of **Barbere** as modified by **Barath** fails to disclose and a second cutting member coupled to the balloon and radially aligned with the second set of longitudinally aligned openings.

However, **A** teaches and a second cutting member (**66**, holes are placed opposite each other on each side of the circle, when used in combination with the Barath patent, the holes are aligned with two sets of cutting members) coupled to the balloon and radially aligned with the second set of longitudinally aligned openings

It would have been obvious to one having ordinary skill in the art at the time the invention was made to align the holes with a second cutting member, since it has been held that a mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Regarding **Claim 7, Barbere** discloses: an inner tubular member (**14**, the inner member, having a lumen) and an outer tubular member, (**12**, the exterior tube) and wherein the inflation lumen (**18**, the balloon) is defined by a space between the inner and outer tubular members.

Regarding **Claim 8, Barbere** discloses: the inner tubular member extends distally beyond a distal end of the outer tubular member. (**10, Fig. 1**, the inner member is found continuing past the end of the outer).

Regarding **Claim 10, Barbere** discloses: the catheter shaft includes a central guidewire lumen, (**14**, the inner member, can be used as a guidewire lumen) and wherein the inflation lumen is disposed in the catheter shaft and positioned radially from the guidewire lumen.

2. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Barath** and **Barbere** as applied to claim 1 above, and further in view of **Saab (US Pg Pub 2006/0106336)**.

Regarding **Claim 5, Barbere** discloses the invention claimed as stated above except for a distal end of the inner tubular member and a distal end of the outer tubular member are substantially aligned.

However, **Saab** teaches a distal end of the inner tubular member and a distal end of the outer tubular member are substantially aligned. (**Fig. 3**, the inner and outer members run together along the whole member)

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to use the construction as taught by **Saab**, since **Saab** states at paragraphs 6-7 that such modification would result in a stronger device. Thus, it would have been obvious to one of ordinary skill in the art to apply the construction as taught in **Saab**, to improve the catheter of **Barbere** for the predictable result of making the device stronger.

3. Claims 9 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Barath, Shaw** and **Barbere** as applied to claim 7 above, and further in view of **Saab**.

Regarding **Claim 9**, **Barbere** discloses the invention claimed as stated above except for a distal end of the inner tubular member and a distal end of the outer tubular member are substantially aligned.

However, **Saab** teaches a distal end of the inner tubular member and a distal end of the outer tubular member are substantially aligned. (**Fig. 3**, the inner and outer members run together along the whole member)

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to use the construction as taught by **Saab**, since **Saab** states at paragraphs 6-7 that such modification would result in a stronger device. Thus, it would have been obvious to one of ordinary skill in the art to apply the construction as taught

in **Saab**, to improve the catheter of **Barbere** for the predictable result of making the device stronger.

Regarding **Claim 11**, **Barbere** discloses the invention claimed as stated above except for a second inflation lumen disposed in the catheter shaft and positioned radially from the guidewire lumen.

However, **Saab** teaches a second inflation lumen disposed in the catheter shaft and positioned radially from the guidewire lumen. (**Fig. 11**, multiple lumens are found here)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use multiple inflation lumens, since it has been held that a mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Regarding **Claim 12**, **Barbere** discloses the invention claimed as stated above except for the inflation lumen is in fluid communication with the first set of longitudinally aligned slots and wherein the second inflation lumen is in fluid communication with the second set of longitudinally aligned slots.

However, **Shaw** teaches the inflation lumen is in fluid communication with the first set of longitudinally aligned slots and wherein the second inflation lumen is in fluid communication with the second set of longitudinally aligned slots. (**Fig. 4 and 5**, equivalencies can be seen between 3 and 4 cutting member designs and if a three member design were used with the device the holes and cutting members could line up all around)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to align the holes with a second cutting member, since it has been held that a mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Regarding **Claim 13, Barbere** discloses the invention claimed as stated above except for one or more inflation lumens disposed in the catheter shaft.

However, **Saab** teaches multiple inflation lumens (**Fig. 11**, multiple lumens are found here)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use multiple inflation lumens, since it has been held that a mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

4. Claims 14-15 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Barbere**.

Regarding **Claim 14, Barbere** discloses: an elongate shaft having a proximal end, (**Fig. 1**, the left hand side) a distal end, (**Fig. 1**, the right hand side) and a guidewire lumen (**14**, the inner member, can be used as a guidewire lumen) extending therethrough; a first side lumen (**12**, the exterior tube) defined in the shaft and extending therethrough; a first longitudinally-aligned set of openings (**22**, multiple opening at the distal end) defined in the shaft and in fluid communication with the first side lumen; a balloon (**18**, the balloon) coupled to the shaft and disposed over the first and second sets of openings;

Barbere fails to disclose a cutting member, a second side lumen defined in the shaft and extending therethrough; a second longitudinally-aligned set of openings defined in the shaft and in fluid communication with the second side lumen.

However, **Barath** teaches one or more cutting members (**6**, a cutting member)

The device of Barbere as modified by Barath fails to disclose the plurality of openings.

However **A** teaches a plurality of openings (**66**, 3 openings on each side can be seen)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a second set of lumen and holes, since it has been held that a mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Regarding **Claim 15**, **Barbere** discloses the invention claimed above except for a set of three holes.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use three holes, since it has been held that a mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Regarding **Claim 21**, **Barbere** discloses: an elongate shaft having a proximal end, (**Fig. 1**, the left hand side) a distal end, (**Fig. 1**, the right hand side) and a guidewire lumen (**14**, the inner member, can be used as a guidewire lumen) extending therethrough; a first side lumen (**12**, the exterior tube) defined in the shaft and extending

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therethrough; a first longitudinally-aligned set of openings (**22**, multiple opening at the distal end) defined in the shaft and in fluid communication with the first side lumen; a balloon (**18**, the balloon) coupled to the shaft and disposed over the first and second sets of openings; and a cutting member coupled to the balloon

Barbere fails to disclose a cutting member, a second side lumen defined in the shaft and extending therethrough; a second longitudinally-aligned set of openings defined in the shaft and in fluid communication with the second side lumen.

However, **Barath** teaches one or more cutting members (**6**, a cutting member)

The device of Barbere as modified by Barath fails to disclose the plurality of openings.

However **A** teaches a plurality of openings (**66**, 3 openings on each side can be seen)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a second set of lumen and holes, since it has been held that a mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Regarding **Claim 22**, **Barbere** discloses the invention claimed above except for a set of three holes.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use three holes, since it has been held that a mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

5. Claims 16-18 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Barbere** as applied to claim 14 above, and further in view of **Saab**.

Regarding **Claims 16-18 and 23-25**, **Barbere** discloses the invention claimed as stated above except for the proper shape and number of lumens

However, **Saab** teaches the first side lumen has a half-moon shaped cross-sectional area, (**144, Fig 14, half moon lumens**) the first side lumen has a pill shaped cross-sectional area, (**124, Fig. 14, pill shaped lumens**) and one or more additional side lumens. (**Fig. 14, 9 lumens total**)

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to use the construction as taught by **Saab**, since **Saab** states at paragraphs 6-7 that such modification would result in a stronger device. Thus, it would have been obvious to one of ordinary skill in the art to apply the construction as taught in **Saab**, to improve the catheter of **Barbere** for the predictable result of making the device stronger.

6. Claims 19-20 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Barbere** as applied to claim 14 above, and further in view of **Barath**.

Regarding **Claims 19-20 and 26-27**, **Barbere** discloses the invention claimed as stated above except for the first set of openings is radially aligned with the cutting member.

However, **Barath** teaches the first set of openings is radially aligned with the cutting member. (**6 and 4, Fig. 3, the right hand opening lines up with the cutting member**)

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to the construction design as taught by **Barath**, since **Barath** states at column 2, lines 15-16 and 45-48 that such modification would cause less damage to blood vessels. Thus, it would have been obvious to one of ordinary skill in the art to apply the construction as taught in **Barath**, to improve the catheter of **Barbere** for the predictable result of making the device safer to use.

The device of Barbere as modified by Barath fails to disclose a second set of aligned cutting members.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to align a second set, since it has been held that a mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Applicant's arguments filed 10/22/2008 have been fully considered but they are not persuasive.

Response to Arguments

Applicant states, that Shaw is not valid art, and examiner has withdrawn the rejections.

Applicant states, Barbere and Barath fail to disclose multiple openings; however under the new grounds of rejection, the argument is moot.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN K. HOLLOWAY whose telephone number is (571)270-3862. The examiner can normally be reached on 8-5, Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ian K Holloway/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763